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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/481,207 01/11/00 PHILLIPS

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EXAMINER

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ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 02/23/01 9

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/481,207</b>	Applicant(s) <b>Phillips</b>
	Examiner <b>Jane Fan</b>	Group Art Unit <b>1625</b>

Responsive to communication(s) filed on Oct 4, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

Claim(s) 1-22 is/are pending in the application.

Of the above, claim(s) 2, 3, 8, and 16-22 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 1, 4-7, and 9-15 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Applicant's election with traverse of group I in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the claims are drawn to generic PPI plus a buffer. This is not found persuasive because the proviso statement shows that references disclosed at pages 17-22 of the instant application teach omeprazole in sodium bicarbonate solution. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art (references disclosed at pages 17-22 of the instant application), the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The requirement is still deemed proper and is therefore made FINAL.

The subject matter of PPI being omeprazole in claims 1,4-7, 9-15 has been searched and examined for merits. Claims 2-3, 8,16-22 and the subject matter of claims 1, 4-7, 9-15 wherein PPI being not omeprazole are withdrawn from consideration. 37 CFR1.142(b).

Claims 1, 4-7, 9-15 are rejected as being drawn to Improper Markush groups. Note the above rationale. Deleting the non-elected subject matter would overcome this rejection.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

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having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilbrant et al., Andersson et al.( Page 17, lines 19-27, and page 18, lines 17-25 of the specification ), Landahl et al.further in view of CA 123:208914 for claim 4, and in view of CA 123:237886 for claim 5.

In establishing a case of prima facie obvious, the following is noted:

**Determination of the scope and content of the prior art ( MPEP 2141.01).**

Pilbrant et al., Andersson et al.( Page 17, lines 19-27, and page 18, lines 17-25 of the specification ), Landahl et al. all teach a liquid oral composition containing omeprazole in sodium bicarbonate solution. Pilbrant et al. teaches omeprazole concentration be 1.2 mg/ml. Andersson et al.( Page 17, lines 19-27, and page 18, lines 17-25 of the specification ), Landahl et al.all do not disclose the concentration of omeprazole.

**Ascertainment of the difference between the prior art and the claims ( MPEP 2141.02).**

The difference between Pilbrant et al. and the claims is the former concentration being 1.2mg/ml whereas the latter being greater than 1.2mg/ml which reads on 1.21mg/ml.

**Finding of prima facie obvious--rational and motivation (MPEP 2142-2143)**

It would have been obvious to one skilled in the art to use 1.21-1.3 mg/ml in making more buffer solutions in Pibrant et al. reference. One having ordinary skilled in the art would have been motivated to do with a reasonable expectation of success.

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For claim 4, the use of anti-foaming agent is conventional for acid-sensitive pharmaceutical compounds in a composition. Note CA 123: 208914. For claim 5, the use of flavoring agent is taught in CA 123:237886 anti-acid composition.

The Andersson et al. and Landahl et al. references all teach different concentrations of omeprazole. Person skilled in the medicinal art would be able to formulate appropriate dosages (concentration) for sound medical practice. In order to overcome this rejection, applicants are required to present unexpected advantages with side-by side comparisons between the art concentration and the claimed ones.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 10 12, are rejected under 35 U.S.C. 102(b) as being anticipated by pat' 4,786,505 by Lovgre et al. ( col. 6, line 9-10, Table I ) or CA 119:278792 by Ooishi et al.

Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over pat' 4,786,505 by Lovgre et al.or CA 119:278792 by Ooishi et al.optionally in view of in view of CA 123:208914 for claim 9.

The two primary references all teach the claimed solid composition. Other buffering agents than what are taught in the references would be obvious for person skilled in the art. Adding flavor in a composition is taught in CA 123:208914. In order to overcome this rejection,

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applicants are required to present unexpected advantages with side-by side comparisons between the art buffer agents and the claimed ones.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 15 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claims of prior U.S. Patent No. 5,840,737. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 15 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 5,840,737. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the choice of buffering agent is conventional.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JANE FAN whose telephone number is (703) 308-4705.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

JTF February 22, 2001



JANE FAN  
PRIMARY EXAMINER  
GROUP 1200